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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,383	02/05/2004	Daqing Che	PT2087000	3324
81399	7590	04/01/2009		
Apotex, Inc. 150 Signet Drive Toronto, ON M9L 1T9 CANADA			EXAMINER HUGHES, ALICIA R	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 04/01/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,383	Applicant(s) CHE ET AL.	
	Examiner ALICIA R. HUGHES	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1 and 3-24 are pending and the subject of this Office Action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed 02 March 2009 has been entered.

Applicants' arguments, filed on 02 March 2009, have been fully considered and it is deemed to be persuasive regarding the previous rejection. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Claims 1 and 3-24 are herein acted upon on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejection – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-24 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,087,511 [hereinafter referred to as “Lin et al”](the reference is being considered in its totality)¹.

The teachings of Lin et al as set forth in this Office's Actions of 08 February 2008 and 02 December 2008 are incorporated herein by reference in their entirety.

Applicants insistently argue that Lin et al teaches away from the instant invention, because “the step reversal addition (adding the atorvastatin salt solution to the calcium chloride or calcium acetate solution), as well as Applicants’ direct one step process versus the two step process found in the ‘511 Patent is not obvious to a person of ordinary skill in the art” (Remarks of July 18, 2008, pages 11-12). However, as noted prior, these arguments are not persuasive, most notably, because of the open claim language comprising encompasses the scope of the full invention. Applicants also note unexpected advantages over the prior art. However, in the absence of clear evidence of record, this appears to be but an allegation lacking factual support.

The adjustment of particular conventional working conditions such as quantity of seeds of amorphous atorvastatin calcium relative to the weight percent of atorvastatin lactone and the stoichiometry of sodium hydroxide relative to the same, and the timing of the hydrolysis reaction are mere matters of routine optimization and judicious selection well within the purview of one of ordinary skill in the art.

As a result, one of ordinary skill in the art would have been motivated to perform the instant invention based on the disclosures in Lin et al because as noted therein, although

¹ Lin et al is cited on Applicants' IDS.

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amorphous atorvastatin solids were known to exist in advance of the advent of crystalline atorvastatin, “the production of amorphous atorvastatin by the previously disclosed processes was not consistently reproducible (Col. 1, lines 61-65). Further, it was also known that the bioavailability patterns of drugs often differ based on whether their forms are amorphous or crystalline, for example, making it desirable to have a procedure for converting the crystalline form to the amorphous form (Col. 2, lines 1-7).

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare amorphous atorvastatin calcium by the hydrolysis of atorvastatin lactone to form atorvastatin sodium salt, to suspend the same into a solution of aqueous calcium acetate, and then, to isolate and dry the same to form amorphous atorvastatin calcium salt and that the same would be effective in the treatment of hypercholesterolemia.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614